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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/581,252	12/04/2000	Donald G. Munroe	P108074-0000	4192

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EXAMINER

KEMMERER, ELIZABETH

ART UNIT PAPER NUMBER

1646

DATE MAILED: 06/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/581,252	<b>Applicant(s)</b> MUNROE ET AL.	
	<b>Examiner</b> Elizabeth C. Kemmerer, Ph.D.	<b>Art Unit</b> 1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 11 March 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-4,6-16,18,19,21 and 22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4,6-16,18,19,21 and 22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Status of Application, Amendments, And/Or Claims***

The amendment received 11 March 2004 has been entered in full. Claims 5, 17 and 20 are canceled. Claims 1-4, 6-16, 18, 19, 21 and 22 are under examination.

The sequence listing received 11 March 2004 is free of errors and has been entered into the file.

The proposed correction to Figure 4A received 11 March 2004 is approved.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Withdrawn Objections And/Or Rejections***

The application is now in compliance with the sequence rules, 37 CFR 1.821-1.825.

The rejection of claims 1-16, 18 and 19 under 35 U.S.C. § 112, second paragraph, as set forth at pp. 3-4 of the previous Office Action (mailed 11 September 2003) is *withdrawn* in view of the canceled and amended claims (received 11 March 2004).

### ***35 U.S.C. §§ 101 and 112, First Paragraph***

Claims 1-16, 18, 19, 21 and 22 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a credible, specific and substantial asserted utility or a well established utility.

Claims 1-16, 18, 19, 21 and 22 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a credible, specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

The basis for these rejections is set forth at pp. 4-8 of the previous Office Action (mailed 11 September 2003).

Applicant's arguments (pp. 12-16, amendment received 11 March 2004) have been fully considered but are not found to be persuasive for the following reasons.

Applicant clarifies the discrepancies between nomenclature for EDG receptors used in the instant specification and other research groups. Applicant clarifies that the claimed EDG-5 receptor binds LPA and not S1P. Applicant's assistance in clarifying these issues is greatly appreciated. However, the rejections still stand due to the reasons set forth in the previous Office Action from pp. 6-8.

Applicant argues that the claimed EDG-5 receptor is an inflammatory LPA receptor which induces NF-kB when activated. Applicant refers to WO 99/35259, incorporated by reference, as disclosing this, and also for recognizing activated EDG-5 as a means for controlling apoptosis and inflammatory responses. This has been fully considered but is not found to be persuasive. As stated in the previous Office Action, NF-kB is activated in response to many diverse stimuli and its activation leads to many diverse biological responses (see Sun et al., 2002, of record). The biological responses comprise apoptosis and inflammation. However, it is unclear from the application and

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other evidence of record *how* EDG-5 controls apoptosis and inflammation, and what cells or tissues would be involved. Without this information, the skilled artisan would have to experiment unduly

Applicant refers to Example 3 of the specification that concludes that EDG-5 is capable of inducing inflammatory gene transcription through NF-kB, and for suggesting that the HEDG-5 nucleotide sequence can be used in an assay to detect inflammation associated with abnormal levels of HEDG-5 expression. This has been fully considered but is not found to be persuasive. Example 3 discloses that EDG-5 responds to and LPA ligand, activates NF-kB, and induces SRE and AP-1 reporter constructs. The response to LPA and induction of NF-kB were addressed above. The induction of SRE and AP-1 only further indicates that EDG-5 is involved in inflammation. However, it is still not clear *how* EDG-5 is involved in inflammation, in what cells or tissues it affects inflammation, and what sort of inflammation is affected (e.g., inflammation associated with infection, injury, autoimmune disease, etc.). Significant further research would be required to determine such, and thus the asserted utility regarding a role in inflammation is not substantial.

Applicant concludes that the specification provides a specific and substantial utility by identifying the role of EDG-5 in modulating inflammatory response in relation to LPA binding and activation of NF-kB, such as treatment of inflammatory diseases like rheumatoid arthritis or asthma. Applicant submits that none of the references or assertions made in the Office Action casts doubt on the utility of EDG-5 for controlling inflammatory response which is present in the specification. This has been fully

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considered but is not found to be persuasive. The specification does not disclose *how* EDG-5 modulates inflammation, nor what type of inflammation it affects. Significant further research would be required to determine such, and so the asserted utility that EDG-5 “plays a role” in inflammation is not substantial. It is also not specific, since LPA activates different receptors and is involved in diverse biological activities, as reviewed in the specification at p. 11. Similarly, activation of NF-kB occurs in response to many diverse stimuli and leads to diverse biological responses. The assertion that EDG-5 “modulates” or “plays a role” in inflammation is very general. Therefore, the asserted utility is not specific.

For all of these reasons, the rejections are maintained.

### **35 U.S.C. § 102**

Claims 1-4, 6-13, 15, 16, 18, 19, 21 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Bando et al. for reasons of record (set forth at p. 9 of the previous Office Action, mailed 11 September 2003).

Applicant argues (pp. 16-17, amendment received 11 March 2004) that Bando et al. is unavailable as prior art, in that Applicant is relying upon their claim to priority to parent applications, giving the application an effective filing date of December 23, 1998. Applicant argues that the instant claims should be given benefit of the earlier filing dates since the specifications provide a credible, specific and substantial utility for the claimed invention as well as provide full enablement of the claimed invention. This has been fully considered but is not found to be persuasive because, as discussed above, the

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instant application fails to meet the utility and enablement requirements. Therefore, the claims to priority is denied, and the Bando et al. reference qualifies as prior art under 35 U.S.C. § 102(b).

### ***Double Patenting***

Claims 1-4, 6-16, 18, 19, 21 and 22 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 6,057,126 for the reasons set forth at p. 10 of the previous Office Action (mailed 11 September 2003).

Applicant's indication (p. 17, amendment received 11 March 2004) that a terminal disclaimer will be submitted upon an indication of allowable subject matter is acknowledged. Accordingly, the rejection is maintained and held in abeyance.

### ***Conclusion***

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within

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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth C. Kemmerer, Ph.D. whose telephone number is (571) 272-0874. The examiner can normally be reached on Monday through Thursday, 7:00 a.m. to 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, Ph.D. can be reached on (571) 272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

ECK



ELIZABETH KEMMERER  
PRIMARY EXAMINER